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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,041	10/30/2003	Julia Coronella-Wood	5051.057	7846

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,041	CORONELLA-WOOD, JULIA	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Coronella-Wood, Julia

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-3, as specifically drawn to an isolated polynucleotide encoding a breast cancer-specific antibody fragment including SEQ ID NO: 1 in the reply filed on 04/06/2005 is acknowledged.

Claims 1-11 are currently pending.

Claims 4-11 have been withdrawn from examination as being drawn to non-elected inventions.

Claims 1-3 are currently under consideration.

Information Disclosure Statement

The IDS filed on June 8, 2004, wherein applicants make of record that no prior art document are know to exist is acknowledged. A signed copy of the IDS is attached hereto.

Specification

The disclosure is objected to because of the following informalities: The specification on page 13, lines 13-15 recites "...polynucleotides encoding antibody 16.4.19 (SEQ ID NO: 1)...." and "...polynucleotides encoding antibody 16.4.20 (SEQ ID NO: 2) ...." Thus, it appears that the specification is implying that SEQ ID NO: 1 and 2 are amino acid sequences for the antibodies. However, a review of the sequence listing filed on 10/30/2003 clearly indicates that SEQ ID NOs: 1 and 2 are nucleic acid sequences.

Appropriate correction/clarification is required.

Note: Applicants are reminded that no new matter should be introduced by amendment to the specification, see MPEP 35 USC 132.

Claim Objections

Claims 1-3 are objected to because of the following informalities: In the instant case, the claims as written appear to imply that SEQ ID NO: 1 corresponds to a breast cancer-specific antibody fragment encoded by an isolated polynucleotide. However, the sequence listing filed on 10/30/2003 clearly indicates that SEQ ID NO: 1 is a nucleic acid sequence. Appropriate correction/clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of polynucleotides, which encode a genus of breast cancer-specific antibody fragment, and a genus of polynucleotide fragments that are fully complementary to a corresponding fragment of the polynucleotide, *supra*. However, the written description in this case only sets forth two species of isolated polynucleotides (SEQ ID NOs: 1 and 2) and only a full complement, which encodes breast cancer-specific antibody fragments (SEQ ID NOs 3 and 4; and SEQ ID NOs: 5 and 6 respectfully).

The specification teaches (page 17, lines 14-20) that specific polynucleotides of the invention include, but are not limited to, a multitude of Fab-encoding nucleotide sequences, some bearing minimal homology to nucleotide sequences of any known and naturally occurring genes. Moreover, the specification teaches (page 19, lines 1-6, lines 17+ and page 20, lines 5-13) that the polynucleotides of the invention not only include the nucleotides of SEQ ID NOs: 1 or 2, but also

any hybridization product, any altered nucleic acid sequence which encodes a Fab or any allele encoding a Fab. Furthermore, the specification appears to be silent on any and/or all polynucleotide fragments, which are fully complementary to a corresponding segment of the polynucleotide. Thus, the written description (specification, page 30-31) only reasonably conveys two species of isolated polynucleotides (SEQ ID NOs: 1 and 2) and their full complement associated with encoding breast cancer-specific antibody fragments (SEQ ID NOs 3 and 4; and SEQ ID NOs: 5 and 6 respectfully); and therefore, is not commensurate with the full scope of any polynucleotide or fragment thereof which encode a breast cancer-specific antibody. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of nucleic acids that encompass the genus of polynucleotides which encode a breast cancer specific antibody fragment nor does it provide a description of structural features that are common to the nucleic acids. Furthermore, the specification does not appear to provide a representative number of breast cancer-specific antibody fragments that encompass the genus of antibodies nor does it provide a description of structural features that are common to the antibodies. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of two species of polynucleotides and their corresponding antibody fragments are insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever*

is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of polynucleotides and antibody fragments, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only two species of isolated polynucleotides (SEQ ID NOs: 1 and 2) associated with encoding breast cancer-specific antibody fragments (SEQ ID NOs 3 and 4; and SEQ ID NOs: 5 and 6 respectfully), but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(Note: Due to the indefiniteness of claim 1, for prior art purposes the isolated polynucleotide encoding a breast cancer-specific antibody will be interpreted as any polynucleotide which encodes a breast cancer-specific antibody.)

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Orlani *et al.* (Proc. Natl. Acad. Sci. USA 1989; 86: 3833-3837).

Orlani *et al.* (abstract, page 3836, Fig. 4) teach isolated polynucleotides which encode human mammary carcinoma line specific antibodies. Moreover, the reference teaches a polynucleotide fragment that is fully complementary to a corresponding segment of the polynucleotide (page 3833, 2nd column, *cDNA Synthesis and Amplification*).

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Bowdish *et al.* (US 20030219839A1, filed 09/20/2002).

Bowdish *et al.* disclose a polynucleotide which is 71.4% identical to the instantly claimed polynucleotide of SEQ ID NO: 1 (see sequence comparison) and also, has 100% sequence identity from nucleotides 373 to 797 and 1115 to 1405 to the instantly claimed polynucleotide of SEQ ID NO: 1. Thus, Bowdish et al. disclose a polynucleotide fragment of SEQ ID NO: 1. Although the reference does not specifically teach that the isolated polynucleotide encodes a breast cancer-specific antibody, the claims are drawn to the product *per se* and inherently, such a polynucleotide would encode an antibody because the specification (page 30) teaches that one of the antibody coding regions extends from nucleotide 41 to 697 of SEQ ID NO: 1. Thus, the claimed polynucleotide fragment appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

> subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orlani *et al.* (Proc. Natl. Acad. Sci. USA 1989; 86: 3833-3837) or Bowdish *et al.* (US 20030219839A1, filed 09/20/2002) in further view of Mezes *et al.* (US 6,207,815, 2001).

Orlani *et al.* and Bowdish *et al.* (US 20030219839A1, filed 09/20/2002) teach, as applied to claims 1 and 3 above, isolated polynucleotides, which encode breast cancer-specific antibodies.

Orlani *et al.* and Bowdish *et al.* (US 20030219839A1, filed 09/20/2002) do not teach a hybridization probe comprising the polynucleotide and a detectable label.

Mezes *et al.* teach antibody and antibody fragments which are encoded by polynucleotides (column 5, lines 56-61). Specifically, the patent teaches (column 13, lines 48-60) hybridization probes comprising a nucleotide sequence which is complementary to the target polynucleotide, wherein the probe can be a fragment. Moreover, Mezes *et al.* teach (column 14, lines 44-49) that the hybridization probe can further comprise a detectable label.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce a hybridization probe comprising a polynucleotide and a detectable label in view of Mezes *et al.*. One would have been motivated to do so because as evidenced by Mezes *et al.* (column 13, lines 30-35), DNA sequences whose mRNA hybridizes with a probe allows for the discovery of homologous antibody variable region genes from the same germline gene and thus, it is necessary for probes to be detectable after hybridization with the target sequence. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by using a hybridization probe comprising the polynucleotide as taught by Bowdish *et al.* or Orlani *et al.*, one would achieve a probe that would allow for the identification of DNA sequences having homologous antibody variable region genes.

Therefore, NO claim is allowed.

Note: The polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1 appears to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
5/31/05